Inderide® LA
(propranolol hydrochloride and hydrochlorothiazide)
Long-Acting Capsules

CI 3764-9

Inderide® LA

(propranolol hydrochloride and hydrochlorothiazide) Long-Acting Capsules

No. 455—Each Inderide® LA 80/50 Capsule contains:
Propranolol hydrochloride (Inderal® LA) ..... 80 mg
Hydrochlorothiazide ..... 50 mg
No. 457—Each Inderide® LA 120/50 Capsule contains:
Propranolol hydrochloride (Inderal® LA) ..... 120 mg
Hydrochlorothiazide ..... 50 mg
No. 459—Each Inderide® LA 160/50 Capsule contains:
Propranolol hydrochloride (Inderal® LA) ..... 160 mg
Hydrochlorothiazide ..... 50 mg

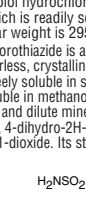
℞ only

DESCRIPTION

Inderide LA is indicated in the once-daily management of hypertension.

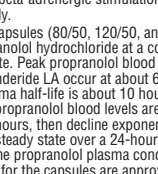
Inderide LA combines two antihypertensive agents: Inderal (propranolol hydrochloride), a beta-adrenergic receptor-blocking agent, and hydrochlorothiazide, a thiazide diuretic-antihypertensive. Inderide LA is formulated to provide a sustained release of propranolol hydrochloride. Hydrochlorothiazide in Inderide LA exists in a conventional (not sustained-release) formulation.

Inderal (propranolol hydrochloride) is a synthetic beta-adrenergic receptor-blocking agent chemically described as 1-(Isopropylamino)-3-(1-naphthyloxy)-2-propanol hydrochloride. Its structural formula is:



Propranolol hydrochloride is a stable, white, crystalline solid which is readily soluble in water and ethanol. Its molecular weight is 295.81.

Hydrochlorothiazide is a white, or practically white, practically odorless, crystalline powder. It is slightly soluble in water; freely soluble in sodium hydroxide solution; sparingly soluble in methanol; insoluble in ether, chloroform, benzene, and dilute mineral acids. Its chemical name is 6-Chloro-3, 4-dihydro-2H-1, 2, 4-benzothiadiazine-7-sulfonamide 1,1-dioxide. Its structural formula is:



Inderide LA contains the following inactive ingredients: calcium carbonate, ethylcellulose, gelatin capsules, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide, and D&C Yellow No. 10. In addition, Inderide LA 80/50 mg and 120/50 mg Capsules contain D&C Red No. 33; Inderide LA 120/50 mg and 160/50 mg Capsules contain FD&C Blue No. 1 and FD&C Red No. 40.

CLINICAL PHARMACOLOGY

Propranolol Hydrochloride (Inderal®)

Inderal is a nonselective, beta-adrenergic receptor-blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor-stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

Inderide LA Capsules (80/50, 120/50, and 160/50 mg) release propranolol hydrochloride at a controlled and predictable rate. Peak propranolol blood levels following dosing with Inderide LA occur at about 6 hours, and the apparent plasma half-life is about 10 hours. Over a 24-hour period, propranolol blood levels are fairly constant for about 12 hours, then decline exponentially. When measured at steady state over a 24-hour period, the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol resulting from the slower rate of absorption of propranolol.

Inderide LA should not be considered a simple mg-for-mg substitute for conventional Inderide Tablets, and the propranolol blood levels achieved do not match (are lower than) those of twice-daily dosing of Inderide Tablets with the same dose. When changing to Inderide LA from conventional Inderide Tablets, a possible need for retitration upwards should be considered.

The mechanism of the antihypertensive effect of propranolol has not been established. Among the factors that may be involved in contributing to the antihypertensive action are: (1) decreased cardiac output, (2) inhibition of renin release by the kidneys, and (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain.

Propranolol hydrochloride decreases heart rate, cardiac output, and blood pressure. Although total peripheral vascular resistance may increase initially, it readjusts to or below the pretreatment level with chronic usage. Effects on plasma volume appear to be minor and somewhat variable.

Inderal has been shown to cause a small increase in serum potassium concentration when used in the treatment of hypertensive patients.

Beta-receptor blockade is useful in conditions in which, because of pathologic or functional changes, sympathetic activity is excessive or inappropriate, and detrimental to the patient. But there are also situations in which sympathetic stimulation is vital. For example, in patients with severely damaged hearts, adequate ventricular function is maintained by virtue of sympathetic drive, which should be preserved. In the presence of AV block, beta blockade may prevent the necessary facilitating effect of sympathetic activity on conduction. Beta blockade results in bronchial constriction by interfering with adrenergic bronchodilator activity, which should be preserved in patients subject to bronchospasm.

The proper objective of beta-blockade therapy is to decrease adverse sympathetic stimulation, but not to the degree that may impair necessary sympathetic support.

Hydrochlorothiazide

Hydrochlorothiazide is a benzothiadiazine (thiazide) diuretic closely related to chlorothiazide. The mechanism of the antihypertensive effect of the thiazides is unknown. Thiazides usually do not affect normal blood pressure.

Thiazides affect the renal tubular mechanism of electrolyte reabsorption. At maximal therapeutic dosage, all thiazides are approximately equal in their diuretic efficacy.

Thiazides increase excretion of sodium and chloride in approximately equivalent amounts. Natriuresis causes a secondary loss of potassium and bicarbonate.

Onset of diuretic action of thiazides occurs in 2 hours, and the peak effect in about 4 hours. Its action persists for approximately 6 to 12 hours. Thiazides are eliminated rapidly by the kidney. The hydrochlorothiazide in Inderide LA is a conventional (not sustained-release) formulation.

INDICATIONS AND USAGE

Inderide LA is indicated in the management of hypertension.

This fixed-combination drug is not indicated for initial therapy of hypertension. Hypertension requires therapy titrated to the individual patient. If the fixed combination represents the dosage so determined, its use may be more convenient in patient management. The treatment of hypertension is not static, but must be reevaluated as conditions in each patient warrant.

CONTRAINDICATIONS

Propranolol Hydrochloride (Inderal®)

Propranolol is contraindicated in: 1) cardiogenic shock; 2) sinus bradycardia and greater than first-degree block; 3) bronchial asthma; 4) congestive heart failure (see "**WARNINGS**"), unless the failure is secondary to a tachyarrhythmia treatable with propranolol.

Hydrochlorothiazide

Hydrochlorothiazide is contraindicated in patients with anuria or hypersensitivity to this or other sulfonamide-derived drugs.

WARNINGS

Propranolol Hydrochloride (Inderal®)

Cardiac Failure: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

In Patients Without a History of Heart Failure, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propranolol should be discontinued (gradually, if possible).

In Patients With Angina Pectoris, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following *abrupt* discontinuance of propranolol therapy. Therefore, when discontinuance of propranolol is planned, the dosage should be gradually reduced and the patient carefully monitored. In addition, when propranolol is prescribed for angina pectoris, the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If propranolol therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Thyrotoxicosis: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

In Patients With Wolff-Parkinson-White Syndrome, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

Major Surgery: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema): PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

Diabetes and Hypoglycemia: Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin. Hypoglycemic attacks may be accompanied by a precipitous elevation of blood pressure in patients on propranolol.

Propranolol therapy, particularly in infants and children, diabetic or not, has been associated with hypoglycemia especially during fasting as in preparation for surgery. Hypoglycemia also has been found after this type of drug therapy and prolonged physical exertion and has occured in renal insufficiency, both during dialysis and sporadically, in patients on propranolol.

Acute increases in blood pressure have occurred after insulin-induced hypoglycemia in patients on propranolol.

Hydrochlorothiazide

Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. In patients with impaired renal function, cumulative effects of the drug may develop.

Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Thiazides may add to or potentiate the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic-blocking drugs.

Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma. The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS

General

Propranolol Hydrochloride (Inderal®)

Propranolol should be used with caution in patients with impaired hepatic or renal function. Propranolol is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that propranolol may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Risk of anaphylactic reaction: While taking beta blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge, either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.

Hydrochlorothiazide

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance, namely: Hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs irrespective of cause are: Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present or during concomitant use of corticosteroids or ACTH.

Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia can sensi-

tize or exaggerate the response of the heart to the toxic effect of digitalis (e.g., increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements, such as foods with a high potassium content.

Any chloride deficit is generally mild and usually does not require specific treatment, except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

Insulin requirements in diabetic patients may be increased, decreased, or unchanged. Diabetes mellitus which has been latent may become manifest during thiazide administration.

If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy.

Thiazides may decrease serum PBI levels without signs of thyroid disturbance.

Calcium excretion is decreased by thiazides. Pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged thiazide therapy. The common complications of hyperparathyroidism, such as renal lithiasis, bone resorption, and peptic ulceration have not been seen. Thiazides should be discontinued before carrying out tests for parathyroid function.

Clinical Laboratory Tests

Propranolol Hydrochloride (Inderal®)

Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

Hydrochlorothiazide

Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.

Drug Interactions

Propranolol Hydrochloride (Inderal®)

Patients receiving catecholamine-depleting drugs, such as reserpine, should be closely observed if propranolol is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Blunting of the antihypertensive effect of beta-adrenoceptor blocking agents by nonsteroidal anti-inflammatory drugs has been reported.

Hypotension and cardiac arrest have been reported with the concomitant use of propranolol and haloperidol.

Hydrochlorothiazide

Thiazide drugs may increase the responsiveness to tubocurarine.

The antihypertensive effects of thiazides may be enhanced in the postsympathectomy patient. Thiazides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Combinations of propranolol and hydrochlorothiazide have not been evaluated for carcinogenic or mutagenic potential or for potential to adversely affect fertility.

Propranolol Hydrochloride (Inderal®)

In dietary administration studies in which mice and rats were treated with propranolol for up to 18 months at doses of up to 150 mg/kg/day, there was no evidence of drug-related tumorigenesis. In a study in which both male and female rats were exposed to propranolol in their diets at concentrations of up to 0.05%, from 60 days prior to mating and throughout pregnancy and lactation for two generations, there were no effects on fertility. Based on differing results from Ames Tests performed by different laboratories, there is equivocal evidence for a genotoxic effect of propranolol in bacteria (*S. typhimurium* strain TA 1538).

Hydrochlorothiazide

Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames bacterial mutagen assay (*S. typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538) or in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations. Nor was it genotoxic *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity), Mouse Lymphoma Cell (mutagenicity) and *Aspergillus nidulans* non-disjunction assays.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diets, to doses of up to 100 mg/kg and 4 mg/kg, respectively, prior to mating and throughout gestation.

Pregnancy: Pregnancy Category C

Combinations of propranolol and hydrochlorothiazide have not been evaluated for effects on pregnancy in animals. Nor are there adequate and well-controlled studies of propranolol, hydrochlorothiazide, or Inderide in pregnant women. Inderide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Propranolol Hydrochloride (Inderal®)

In a series of reproductive and developmental toxicology studies, propranolol was given to rats by gavage or in the diet throughout pregnancy and lactation. At doses of 150 mg/kg/day (>30 times the dose of propranolol contained in the maximum recommended human daily dose of Inderide), but not at doses of 80 mg/kg/day, treatment was associated with embryotoxicity (reduced litter size and increased resorption sites) as well as neonatal toxicity (deaths). Propranolol also was administered (in the feed) to rabbits (throughout pregnancy and lactation) at doses as high as 150 mg/kg/day (>45 times the dose of propranolol contained in the maximum recommended daily human dose of Inderide). No evidence of embryo or neonatal toxicity was noted. Intrauterine growth retardation has been reported in human neonates whose mothers received propranolol during pregnancy. Neonates whose mothers received propranolol at parturition have exhibited bradycardia, hypoglycemia and respiratory depression. Adequate facilities for monitoring these infants at birth should be available.

Hydrochlorothiazide

Studies in which hydrochlorothiazide was orally administered to pregnant mice and rats at doses of up to 3000 and 1000 mg/kg/day, respectively, provided no evidence of harm to the fetus.

Thiazides cross the placental barrier and appear in cord blood. The use of thiazides in pregnant women requires that the anticipated benefit be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions that have occurred in the adult.

Nursing Mothers

Propranolol hydrochloride (Inderal®)

Propranolol is excreted in human milk. Caution should be exercised when Inderide LA is administered to a nursing woman.

Hydrochlorothiazide

Thiazides appear in breast milk. If the use of drug is deemed essential, the patient should stop nursing.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Propranolol Hydrochloride (Inderal®)

Most adverse effects have been mild and transient and rarely have required the withdrawal of therapy.

Cardiovascular: Bradycardia; congestive heart failure; intensification of AV block; hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Light-headedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis; erythematous rash; fever combined with aching and sore throat; laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis; nonthrombocytopenic purpura, thrombocytopenic purpura.

Autoimmune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, LE-like reactions; psoriasiform rashes; dry eyes; male impotence; and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes, and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

Hydrochlorothiazide

Gastrointestinal: Anorexia, gastric irritation, nausea, vomiting, cramping; diarrhea; constipation; jaundice (intrahepatic cholestatic jaundice); pancreatitis; sialadenitis.

Central Nervous System: Dizziness, vertigo; paresthesias; headache; xanthopsia.

Hematologic: Leukopenia; agranulocytosis; thrombocytopenia; aplastic anemia.

Cardiovascular: Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or narcotics).

Hypersensitivity: Purpura; photosensitivity; rash; urticaria; necrotizing angiitis (vasculitis, cutaneous vasculitis); fever; respiratory distress, including pneumonitis; anaphylactic reactions.

Other: Hyperglycemia; glycosuria; hyperuricemia; muscle spasm; weakness; restlessness; transient blurred vision.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

OVERDOSAGE OR EXAGGERATED RESPONSE

The propranolol hydrochloride (Inderal) component may cause bradycardia, cardiac failure, hypotension, or bronchospasm.

The hydrochlorothiazide component can be expected to cause diuresis. Lethargy of varying degree may appear and may progress to coma within a few hours, with minimal depression of respiration and cardiovascular function, and in the absence of significant serum electrolyte changes or dehydration. The mechanism of central nervous system depression with thiazide overdosage is unknown. Gastrointestinal irritation and hypermotility can occur; temporary elevation of BUN has been reported and serum electrolyte changes could occur, especially in patients with impairment of renal function.

Treatment

The following measures should be employed:

General: If ingestion is, or may have been, recent, evacuate gastric contents, taking care to prevent pulmonary aspiration.

Bradycardia: Administer atropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.

Cardiac Failure: Digitalization and diuretics.

Hypotension: Vasopressors, e.g., levarterenol or epinephrine.

Bronchospasm: Administer isoproterenol and aminophylline.

Stupor or Coma: Administer supportive therapy as clinically warranted.

Gastrointestinal Effects: Though usually of short duration, these may require symptomatic treatment.

Abnormalities in BUN and/or Serum Electrolytes: Monitor serum electrolyte levels and renal function; institute supportive measures, as required individually, to maintain hydration, electrolyte balance, respiration, and cardiovascular function.

DOSAGE AND ADMINISTRATION

The dosage must be determined by individual titration.

Hydrochlorothiazide can be given at doses of 12.5 to 50 mg per day when used alone. The initial dose of propranolol is 80 mg daily, and it may be increased gradually until optimal blood pressure control is achieved. The usual effective dose, when used alone, is 160 to 480 mg per day.

One Inderide LA Capsule once a day can be used to administer up to 160 mg of propranolol and 50 mg of hydrochlorothiazide. For doses of propranolol greater than 160 mg, the combination products are not appropriate because their use would lead to an excessive dose of the thiazide component.

Inderide LA provides propranolol hydrochloride in a sustained-release form and hydrochlorothiazide in conventional formulation, for once-daily administration. If patients are switched from Inderide Tablets (or Inderal plus hydrochlorothiazide) to Inderide LA, care should be taken to ensure that the desired therapeutic effect is maintained. Inderide LA should not be considered a mg-for-mg substitute for Inderide or Inderal plus hydrochlorothiazide. Inderide LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

When necessary, another antihypertensive agent may be added gradually, beginning with 50% of the usual recommended starting dose, to avoid an excessive fall in blood pressure.

HOW SUPPLIED

Each beige capsule, identified by one wide band and 3 narrow bands, all in gold, and "Inderide LA 80/50", contains 80 mg of propranolol hydrochloride (Inderal® LA) and 50 mg of hydrochlorothiazide, in bottles of 100 (NDC 0046-0455-81).

Each beige/brown capsule, identified by one wide band and 3 narrow bands, all in gold, and "Inderide LA 120/50", contains 120 mg of propranolol hydrochloride (Inderal® LA) and 50 mg of hydrochlorothiazide, in bottles of 100 (NDC 0046-0457-81).

Each brown capsule, identified by one wide band and 3 narrow bands, all in gold, and "Inderide LA 160/50", contains 160 mg of propranolol hydrochloride (Inderal® LA) and 50 mg of hydrochlorothiazide, in bottles of 100 (NDC 0046-0459-81).

Store at room temperature (approximately 25C). Protect from light, moisture, freezing, and excessive heat. Dispense in a tight, light-resistant container as defined in the USP.

The appearance of these capsules is a registered trademark of Wyeth-Ayerst Laboratories.

Ayerst Laboratories Inc.
A Wyeth-Ayerst Company
Philadelphia, PA 19101

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